Opening Statement of the Honorable Fred Upton
Subcommittee on Oversight and Investigations
Hearing on "A Continuing Investigation into the Fungal Meningitis Outbreak and Whether It Could Have Been Prevented"
April 16, 2013

(As Prepared for Delivery)

I thank Chairman Murphy for convening this important hearing on the deadly outbreak of fungal meningitis, so that this committee can get answers to the question we could not at the last hearing: what did FDA know about NECC and Ameridose? And what did FDA do about it?

When Commissioner Hamburg appeared before us last November, 32 innocent Americans had perished. Today, the death toll stands at 53 and continues to grow. Hundreds are still sick and suffering. An unthinkable, public health disaster keeps on getting worse. My home state of Michigan has been hit the hardest by the fungal meningitis outbreak. According to the CDC, 15 of the 53 people who died after receiving NECC's contaminated products are from Michigan, including 3 from my district. 259 of the 730 people who are sick and suffering from infections are from my state. Just a few weeks ago, Michigan Attorney General Bill Schuette announced that he planned to convene a grand jury to investigate possible criminal charges.

Criminal cases will rightfully examine the company's liability for this tragedy. But it is our job at this committee to also take a hard look at the agency under our jurisdiction, the FDA, and ask: did its processes work? Did the agency do its job and protect the public health? Before we get to the matter of additional authorities and new legislation, we have to ensure that the agency is going to be ready to implement them properly. It is not enough or right just to do something for the sake of doing something. We have to do something that is truly effective.

It took months for the FDA to fully cooperate and provide the necessary documents, but now we finally have them. Commissioner Hamburg, I am troubled by what I have learned. FDA received complaint after complaint about these companies. FDA's documents paint a picture of two companies who appeared to be acting more like manufacturers than compounders. Doctors and other providers made complaints about the sterility of their products. FDA district staff pushed to go back out and re-inspect these companies or take other enforcement action, but in most cases, it didn't happen. It is this breakdown that concerns me the most. "Job one" for the FDA is making sure the medicines we take are safe, but this mission seemed to be lost, as delays prevented the FDA from taking decisive action and the agency took years to finalize its guidance and regulatory documents. We now know that 53 Americans did not need to die. It sickens me that this could have been prevented.

Commissioner Hamburg, we met last week. I share your hope that this is a constructive hearing. We need to get all the facts on the table, and I hope you will help us, so we can move forward. We owe it to the families who lost loved ones and we owe it to those 730 Americans who are still suffering and may never return to leading healthy lives.

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